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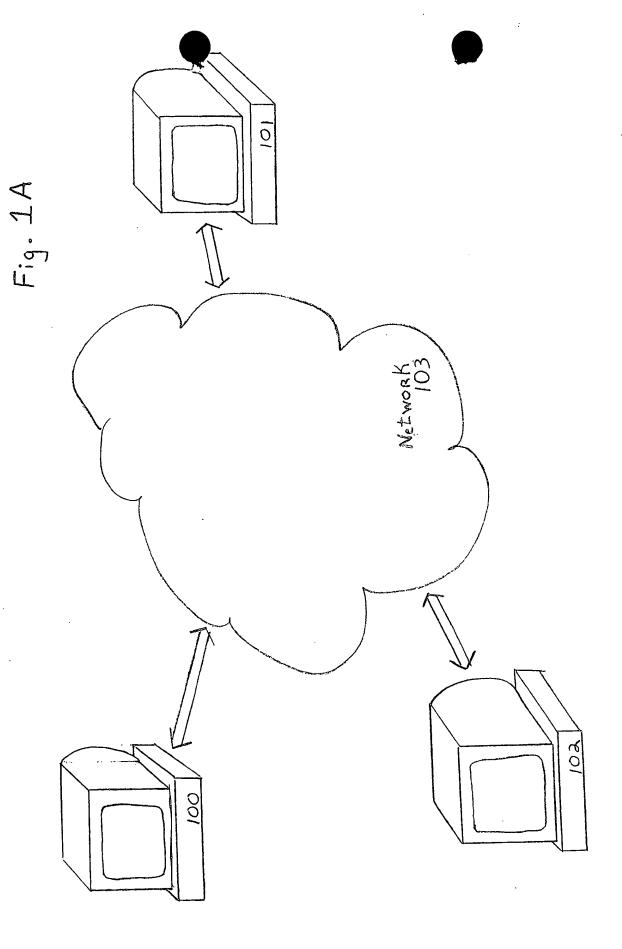
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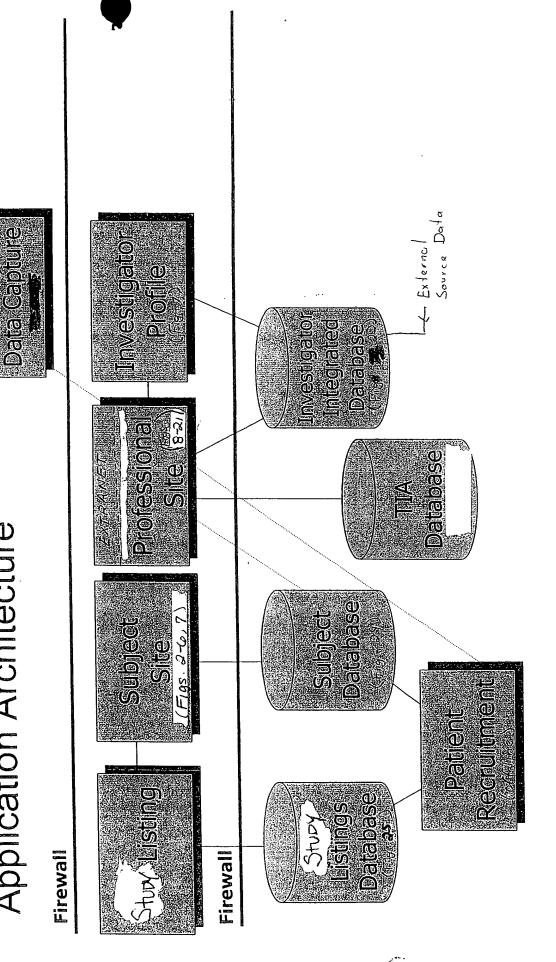
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- Exclusive interactive tools, including your own personal library of news information
- Emails informing you of updates to our clinical trial listings, news and information, tailored to your selection.
- A personal profile used to optimize your experience

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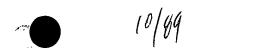
- Introduction: What are clinical trials?
- Why are clinical trials important?
- The clinical trial process.
- How are participant's rights and safety protected during a clinical trial?
- Who pays for clinical trials?
- Where can you get more information about clinical trials?
- Questions you need to ask.
- Common terms used in clinical trials.

Introduction: What are clinical trials?

Quite simply, a clinical trial is a very carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.

When a promising new medication is identified, the drug undergoes careful evaluation for safety and effectiveness through the clinical trial process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. The pharmaceutical or biotechnology company that is sponsoring the trial reports their findings to the U.S. Food and Drug Administration (FDA). The FDA reviews those findings and if they determine that the drug is both effective and safe to use, then they will make the

Fig.



drug available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

If you are looking for clinical trials that may be beneficial for you, please search our clinical trials listing for details on type and location. This is the first step to review the exciting medical research on the potential new treatments of tomorrow that may benefit you today.

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Why are clinical trials important?

Clinical trials are important to increase medical knowledge and find better ways to help people. Generally, the goal of clinical trials is to introduce an investigational treatment that is safer and more effective than the standard treatment for a particular disease or condition. In addition, for those diseases for which there are no treatment options, research and clinical trials may be the only avenue to uncover a potential treatment.

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The clinical trial process.

After a drug is successfully tested in laboratory and animal studies, the FDA grants approval for testing to begin in humans. The testing of drugs in clinical trials - also called clinical studies or clinical research - usually occurs in three and sometimes four different phases or steps. Each phase normally involves a larger number of people.

Phase I. In Phase I trials, researchers study how quickly an investigational treatment works and how the human body processes the investigational treatment. They also try to find dose ranges that will produce the desired effects. Phase I trials typically involve healthy volunteers, but sometimes severely ill patients will participate in these trials.

Phase II. In these trials, the safety and effectiveness of an investigational treatment is studied in larger groups of people who have the disease or condition to be treated.

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Phase III. In Phase III trials, the safety and effectiveness of an investigational treatment are studied in larger populations of people for whom the drug is intended. Typically, there are hundreds or thousands of people in a Phase III trial. Often, the investigational treatment is compared with standard treatments in hopes of finding better ways to help people. The pharmaceutical or biotechnology company that is sponsoring the trial reports the findings from Phase III trials to the U.S. Food and Drug Administration (FDA).

Phase IV. Phase IV trials are also called post-marketing trials. Only after the FDA has determined that the medicine is both safe to use and equivalent or superior to existing therapies is it then made available for broader use by physicians and their patients. Phase IV trials take place after a drug has been approved. Findings from Phase IV trials provide additional information about the safety and efficacy of the drug.

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How are participant's rights and safety protected during a clinical trial?

The FDA is the government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The rights and safety of people participating in clinical trials are also protected by an Institutional Review Board and by an informed consent form. An Institutional Review Board (IRB) is comprised of both physicians and lay people for the purpose of studying the design of the trial and ensuring that participant's rights are maintained. The informed consent form explains the clinical trial and outlines a participant's rights. You should always be given an informed consent form prior to enrolling in any clinical trial.

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Who pays for clinical trials?

- Sponsors fund clinical trials. This funding can come from the federal government via the National Institutes of Health (NIH) or directly from pharmaceutical and biotech companies.
- The clinical trial sponsor contracts with specialized physicians and/or researchers to administrate the trial. Settings for the trials could range from the physician's office to a hospital or research facility. Reimbursement for this service is typically paid out on a per-patient basis.
- Sponsors may pay you to participate in a clinical trial.
 Typically, these fees, when provided, are nominal.
- Medical care is often provided at no cost to the



patients, but they still may be responsible for other expenses such as travel between their homes and the healthcare facility.

Patients may also have to pay for some medical procedures, tests, or hospital stays if these are considered a part of standard treatment and not part of the clinical trial. Before you enroll, you should determine exactly who pays for what services.

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Where can you get more information about clinical trials?

If you or someone you know has a medical problem and is thinking about taking part in a clinical trial, speak to your healthcare provider first. In taking an active role in the management of your health, you may want to work closely with your provider to find out if a particular clinical trial is right for you.

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Questions you need to ask.

- What is the length of your involvement in the clinical trial? How long will the trial last?
- Where will you have to go in order to participate in the clinical trial?
- What are the possible treatments you may receive while in the clinical trial?
- Do the treatment alternatives they provide cover all possible treatments for this disease? If not, what are your other treatment alternatives?
- What procedures are built into the study to keep you safe from harm while you are participating?
- What are the risks and benefits of participating in the clinical trial?
- If there are risks, what will happen should you have an adverse reaction to the treatment in the study?
- What costs may you incur if you participate?
- Will the treatment be available to you even after the clinical trial has concluded?
- Where are the funds coming from to conduct this trial? What is their purpose in sponsoring the trial?

You should also feel free to ask any other question about the trial you want answered.

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Common terms used in clinical trials.

Clinical trial: A clinical trial - also called a clinical study or clinical research - is a way to evaluate the safety and

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benefits of a new drug in a carefully controlled setting. The new drug is tested in people who volunteer to participate in the trial.

Clinical investigator: A clinical investigator is a doctor or scientist who is responsible for carrying out the planned research activities for a clinical trial. Typically, the doctors chosen for these clinical activities are experts within their medical specialties.

Coordinator: A coordinator is a person (usually a nurse or other medical professional) who is responsible for organizing the planned clinical research activities for a trial. The coordinator is also responsible for taking care of important study documents.

Food and Drug Administration: The Food and Drug Administration is often referred to as the FDA. The FDA is a government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The FDA also enforces the laws that govern the approval, regulation and monitoring of drugs and medical devices.

Informed consent: Informed consent is a process that confirms a patient understands the nature of the study, the risks involved, and the expected benefits of treatment. A written and dated form called the "informed consent form" is signed by a patient to document this process.

Institutional Review Board: An Institutional Review Board is usually referred to as the "IRB." The IRB is a group of medical, scientific, and nonscientific people that are responsible for reviewing and approving the planned clinical activities of a study. The group ensures the protection of the rights, safety, and well-being of patients who volunteer for clinical trials.

Investigational treatment: Investigational treatment is another term for the drug, treatment, or medical device that is studied in a clinical trial.

Principal investigator: The principal investigator is the doctor or researcher who is put in charge of all clinical activities at a particular study location and who supervises the care of patients in the study.

Protocol: A protocol is a plan that contains guidelines for a clinical study. The pharmaceutical or biotechnology company that discovered the investigational treatment usually develops the protocol.

Sponsor: The sponsor is the organization that funds a clinical trial and that develops a plan for the research. The organizations can be a pharmaceutical or biotech company, a research institution, or other health organization.

Standard treatment: Standard treatment is a term that refers to approved medical procedures, drugs, tests, or hospitalizations that are a part of the general care considered to be appropriate for certain diseases and conditions. It is the 'best treatment' currently known for a given disease. If there are no current treatments shown to be effective against a particular disease, then no treatment would be the standard treatment for that condition.

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evaluation of the safety and effectiveness of the drug then occurs in the clinical trials process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. Findings from the clinical trials are reported by the pharmaceutical or biotechnology company that is sponsoring the clinical trial to the US Food and Drug Administration — the FDA. Only after the FDA has determined from reviewing the findings from clinical trials that the medicine is both safe to use and effective is it then made available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

If you are looking for information on where clinical trials are taking place and the types of trials that are available, you can search our clinical trials listing. If you want to learn more about clinical trials, please see our About Clinical Trials page. These are the first steps in learning about clinical trials and in deciding how medical research on

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clinical trials and in deciding how medical research on possible treatments for tomorrow may help you today.

About Clinical Trials will provide you with more information.

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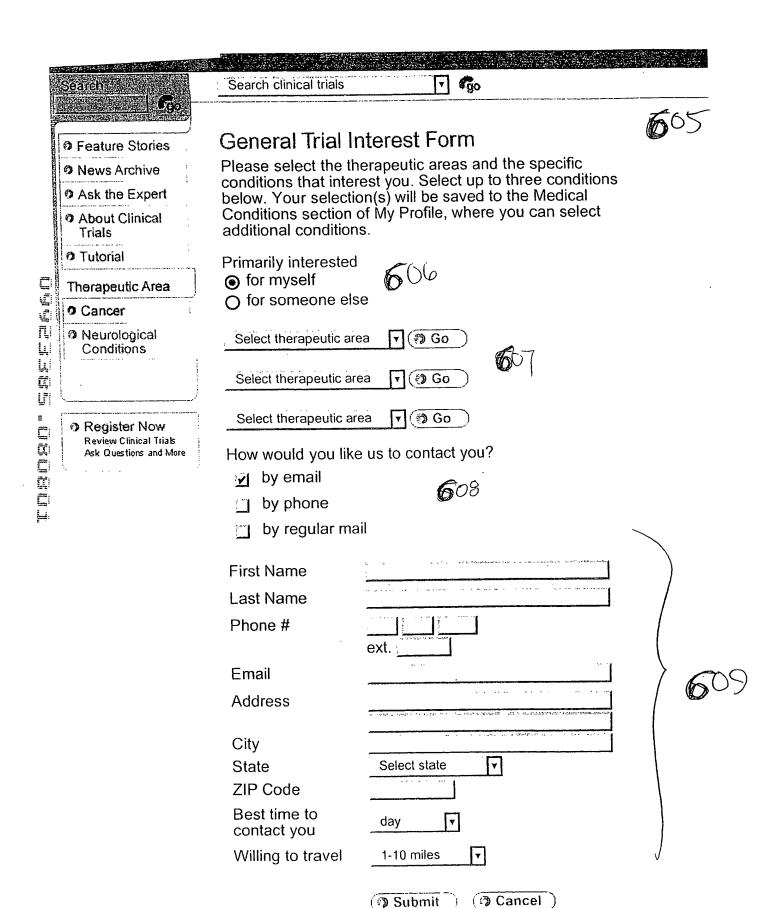


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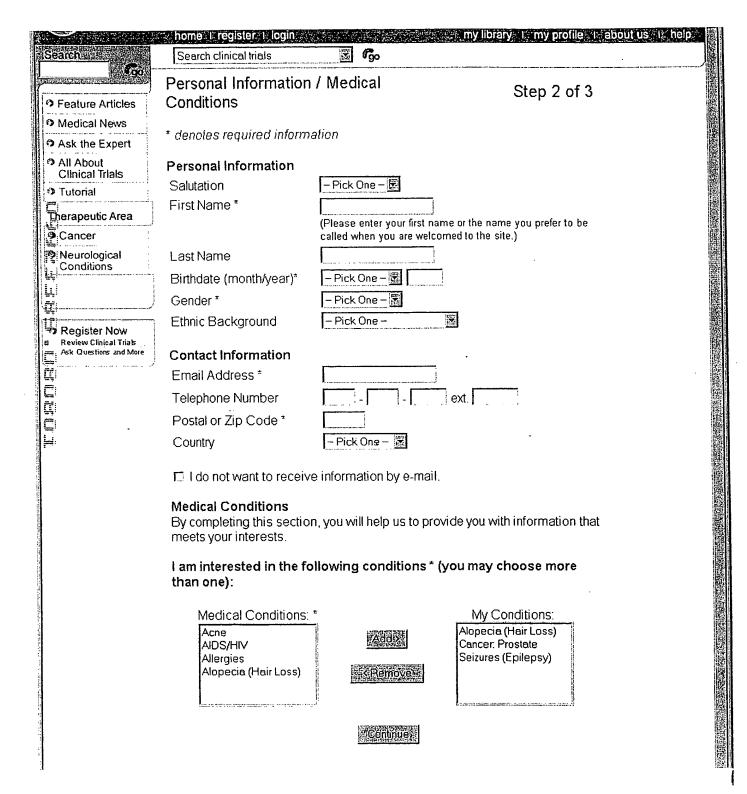
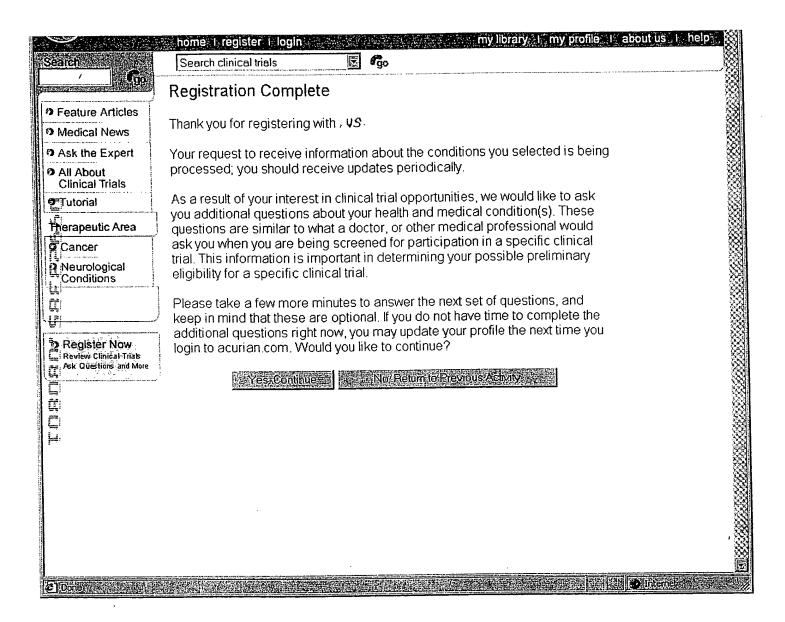


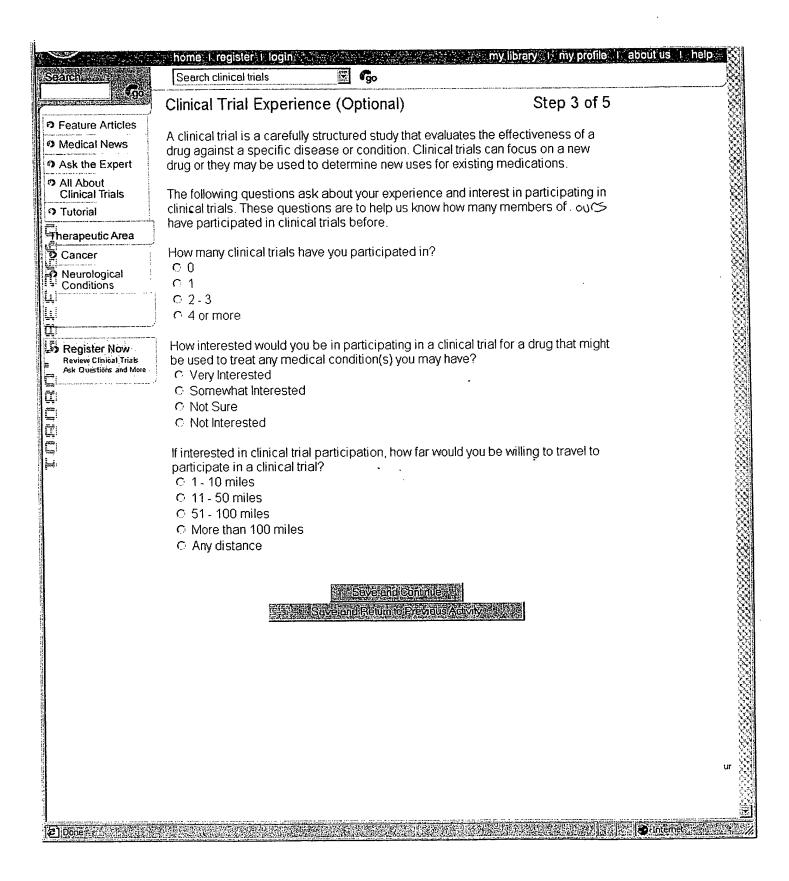
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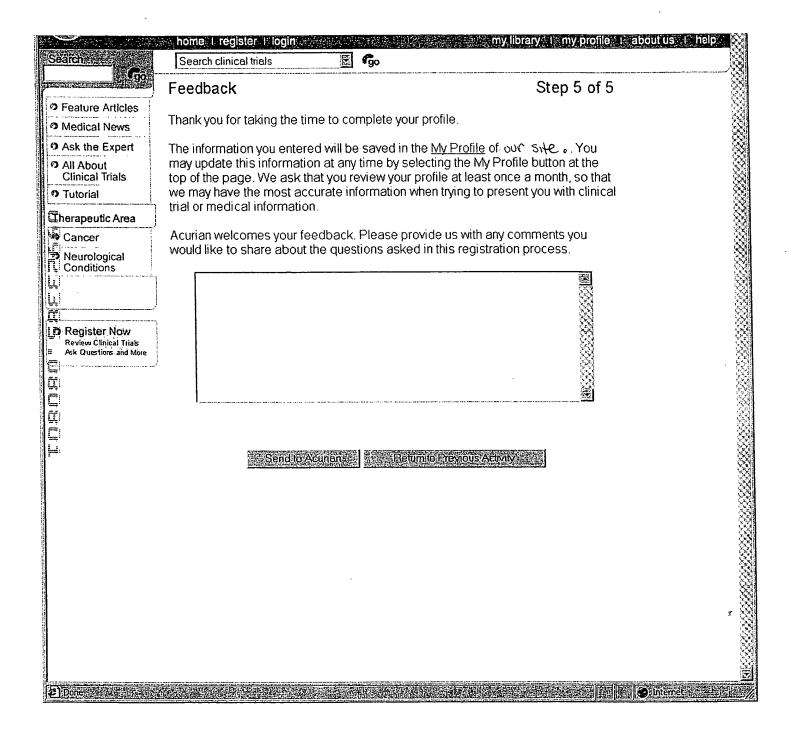
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Peature Articles	It is often important to know your health hab	nite when presenting you with possible
Medical News	clinical trial opportunities	one when presenting you with possible
Ask the Expert	omnoor the opposite the	
All About Clinical Trials	How often do you exercise? O Never	
Tutorial	C Once a week	
Therapeutic Area	○ Twice a week	
***	C Three times a week	
Cancer	C Four or more times a week	
Neurological Conditions	© Daily	
	How often do you visit your primary care p	hysician?
T	O Once a year	
O Register Now	C 2-4 times a year	
Review Clinical Trials	C Every month C I do not have a primary care physician	
Ask Questions and More	The hot have a primary care physician	
	Do you smoke cigarettes?	
==: ==:	○ No, I have never smoked	
<u>m</u> .,	○ No, I quit smoking	
	C Yes, daily	
	← Yes, occasionally	
	If you smoke, how many cigarettes do you	smoke per day?
	Please enter: Cigarettes Per Day	
	If you smoke, how old were you when you	started smoking?
	Please enter. years old	g.
	Do you drink alcoholic beverages?	
	O No	
	○ Yes, occasionally○ Yes, 1-2 drinks per day	
	C Yes, more than 2 drinks per day	
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	C Fair	
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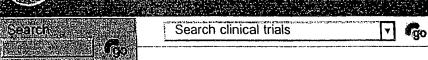
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(OC	Clinical Trial Questions	Step 4 of 5
9 Feature Articles		and interact in clinical trial
n Medical News	Earlier in the registration process, you expres opportunities. When you are screened for a c	
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All About Clinical Trials	for which you have been diagnosed. Your ans help determine if you may potentially qualify for	
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Therapeutic Area	Listed below are the conditions you selected answer questions about each condition, a ch	
2 Cancer	Your information will be saved after you comp	olete each section. If you are unable
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Peature Articles Medical News Ask the Expert All About Clinical Trials Therapeutic Area Cancer Neurological Conditions Register Now Review Clinical Trials Ask Questions and More	Thank You Your message was sent successfully. Thank you for contacting , U.S., Your comments will help us serve you better.





Home / Knowledge Center /

Welcome to My Library

Here's your chance to create a library of your very own. My Library is where you can store all kinds of information found throughout the site. Whether it's clinical trial information, abstracts on news articles, drug information, perspectives from our medical experts or personal stories, links to the items you select will be saved in this area for as long as you choose to keep them there. All you have to do is click the "Save to My Library" button found throughout the site.

In addition, you can type in personal notes along with the items you save. We will not access, use, or review your personal notes for any reason.

If you'd like to go directly to one of the five sections, select a link below:

- News
- Drug Information
- O Clinical Trials
- Ask The Expert
- Feature Stories
- Do not show this page again.

Tutorial Therapeutic Area Cancer Neurological Conditions

Register Now Review Clinical Trials Ask Questions and More

Peature Stories

News Archive

Ask the Expert

About Clinical

Trials



/ / _ / Investigator Questionnaire **Investigator Questionnaire** Step 1 of 3 Thank you for your interest in joining our investigator database. The following questionnaire will take approximately one hour to complete. The privacy and security of your information is important to us. All information you submit is transmitted over a secure server. Register For more information, read our _. Services Asterisks (*) denote required fields. TAQ Last Name * First Name * Middle Name Degree(s) * Primary Research Facility's Organization or Institutional Name * Street Address * City * -- Select State/Province --State / Province / Region ||| Country * -- Select Country --Zip Code / Postal Code * Phone (with area code) * Telephone Extension Fax (with area code) **Email Address** Primary Specialty * -- Select One -Board Certification(s) * O Yes O No Year of Certification Board Eligible * O Yes O No Sub Specialty O Yes O No Board Certification(s) Year of Certification O Yes O No Board Eligible Number of years Investigator has participated in trials? *

FIG 7A

Indicate all phases of clinical research in which the Investigator participated * How many investigators conduct research at this PRF? * Is the Investigator affiliated with: (check all that apply) If affiliated with a local IRB, what is its name?	
Is the Investigator affiliated with: Local IRB Central IRB affiliated with: IEC (Canadian sites only) If affiliated with a local	
affiliated with: (check all that apply) If affiliated with a local	
- I	
How often does the local)
If "other", frequency of local IRB meeting?	
How soon after the IRB meeting will you receive an approval letter?	
Has the Investigator ever been audited by the Food & Drug Administration (FDA) or any other regulatory agency? O Yes O No	
1. If yes, what was the date of the audit?	
Who was the auditor?	0
If audited, was a 483 O Yes O No issued?	ä
What were the results of the audit?	
2. If yes, what was the date of the audit?	
Who was the auditor?	
If audited, was a 483 O Yes O No issued?	
What were the results of the audit?	

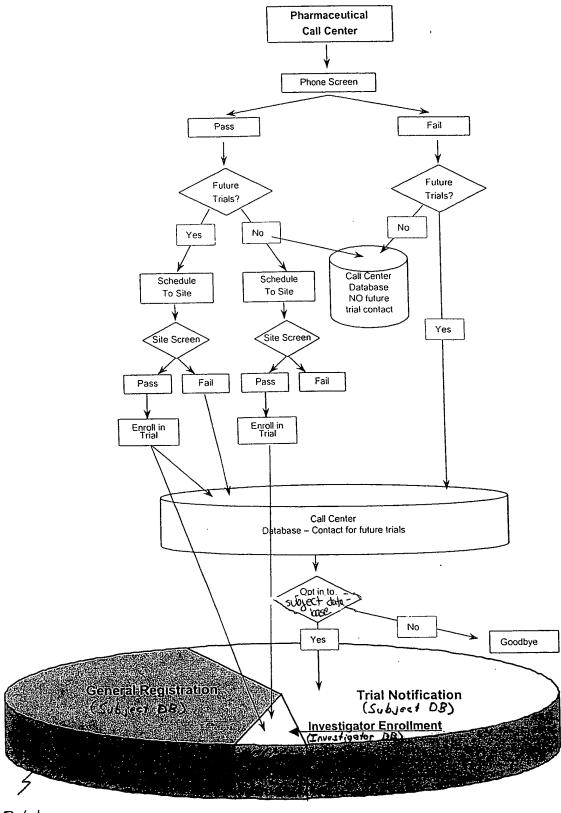
FIG. 7B

3//4	39	
Has the Investigator gone through an audit by a sponsor or CRO?	O Yes O No	
1. If yes, what was the date of the audit?		
Who was the auditor?		~1/O
What were the results of the audit?		110
2. If yes, what was the date of the audit?		
Who was the auditor?		
What were the results of the audit?		
·•	***************************************)
Is your PRF	☐ Single specialty ☐ Multi-specialty	
If PRF is multi-specialty, indicate specialties. (one per line)		
Is your facility part of	☐ Solo practice ☐ Group practice	
Is the facility affiliated with a Site Management Organization (SMO) or research group? If affiliated, please specify the SMO name If affiliated, is this an exclusive relationship?	O Yes O No O Yes O No	
(?) Cancel	Save and Continue	

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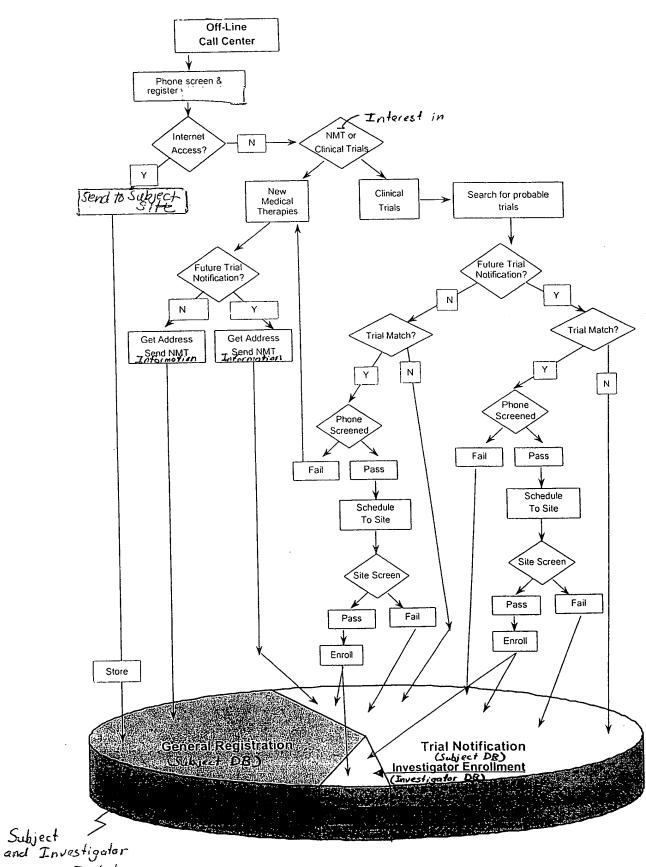
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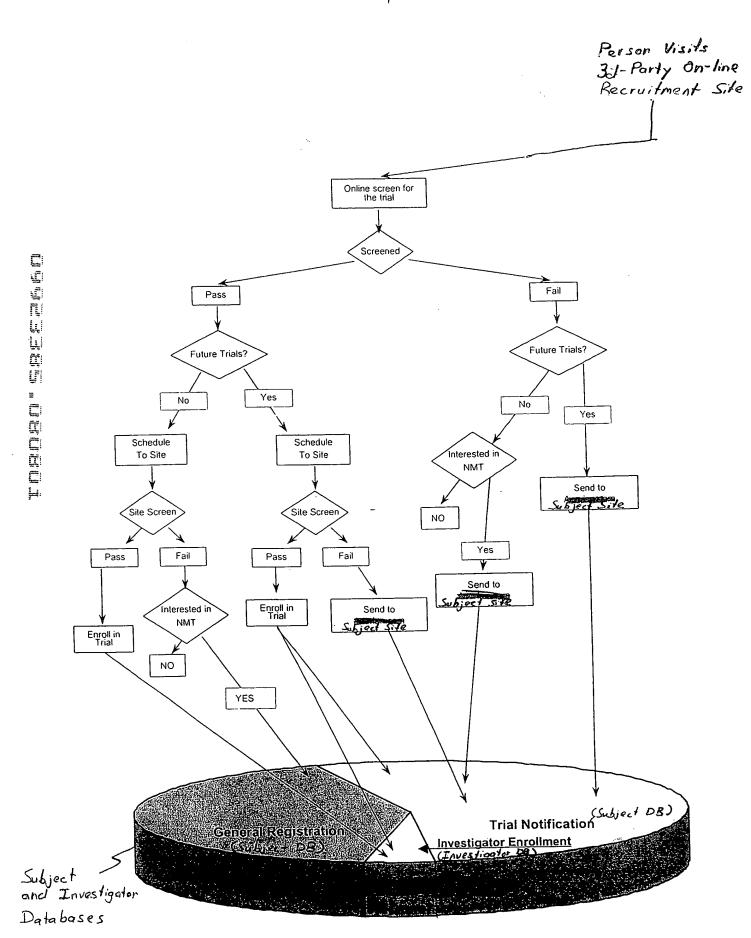
Subject and Investigator Databases

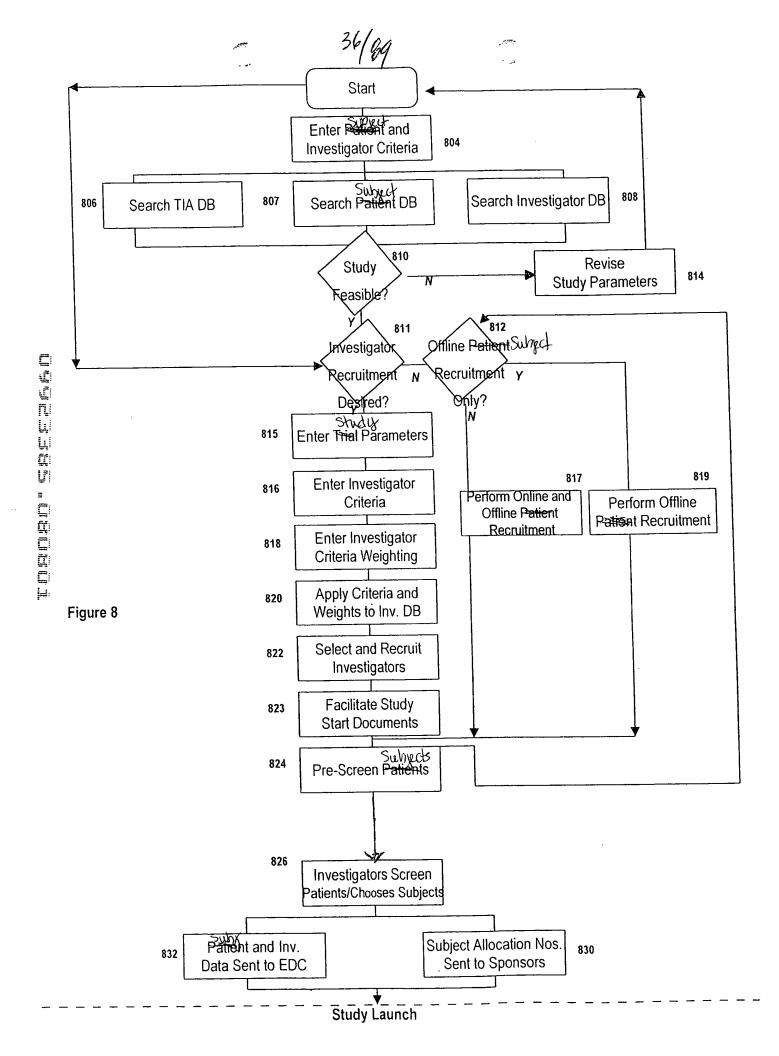
Fig. 7E



Datobases

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		ctive Trials files for a specific protocol please (from a drop down box) information to create s.

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Register		All fields required
3 Services	Protocol Number	
	Protocol Title	₽
Frank	Therapeutic Area	Select a Therapeutic Area ▼
	Disease Indication	Select an Indication ▼
	Projected Number of Sites	
	Projected Number of Patients per Site	
	Projected Trial Start Date	January ▼ 2000 ▼ (Month/Year)
	Projected Trial Stop Date	January 2000 (Month/Year)
	Projected Enrollment Period (in months)	·
	Trial Phase	Select Trial Phase v
	(Save & Search for Investigators

 \underline{P}

Step 1:

To identify potential investigators - please select a specialty.

Nate: To select more than one specialty, point to the specialty and press control click. Limit of 2 selections.

Adolescent Medicine
Aerospace Medicine
Allergy & Immunology

Step 2:

To include the prescribing behavior data in the investigator search results class relevant to the therapeutic area and indication.

Nate: To belect more than one drug class, point to the specialty and press control cless timit of 2 pelections. Acne Therapy
Aids Therapies
All Other Misc. Ethical Drugs

Step 3:

To include the number of trials conducted by the investigator in the search a number.

1 🕏

Step 4:

Patient Therapeutic Area

ا <u>چ</u>

Patient Disease Indication

Patient Disease Indication Encounter Category

Nate: To belect more than one patient deceme indication encounter category, point to the specialty and press control effect. Limit of 2 palections.

-Select a Category-

Case Load Estimates - Malignancy of heptobiliary system of pancreas Inpatient Discharge Diagnosis - Malignant neoplasm of pancreas

Patient Distance from Site (in miles)

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Step 5:

To limit search by geographical location- please enter your selections belo

Municipal Area

–Select a Municipal Area – 🧝

Fig. 10

Walter Comments

Home .

/ <u>Active Trials</u> / <u>Trial At A Glance</u> / Search

Investigator Search Results

The following investigator search results reflect the investigator search enterla and the patient demographic data selected in the investigator Search. Review selections by scrolling down this page or by clicking here: https://link.com/. Click a column heading to sort by that column.

Displaying 1-20 out of 682 results

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Search Results:

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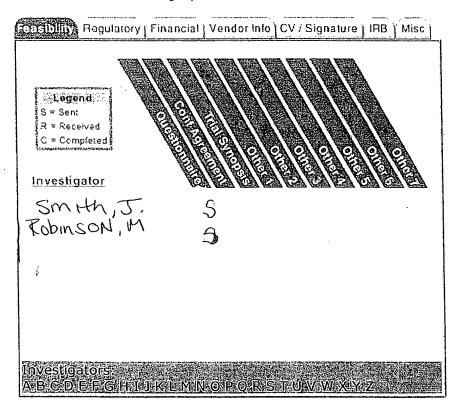
- Document Summary
- Document View
- Investigator View

contact us I help

Home , _____ / Active Trials / Trial at a Glance / Document Tracking

A multi-center study... Document Summary

Summary of document status for the selected protocol. Click on any document to go to Document View by Investigator. Click on any investigator to go to specific Investigator Document View. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.



Return to Trial at a Glance

F16, 12

contact us 1 help

Home /

Active Trials / Trial at a Glance / Document

Tracking / Document View by Investigator

Document View by Investigator

Summary of document status by investigator. Click on any investigator to go to document history of the document selected in the drop down box. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.

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- Register
- Services) FAQ
- > Document Summary
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- View Investigator View

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From: Service Provider

Sent: June 6, 2000

To: Ms. Moore

Subject: Clinical Trial Opportunity

Dear Ms. Moore:

You may qualify for an upcoming clinical trial opportunity. For additional information go to https://www.website.com/study/zz-234567-22* and complete the study specific questionaire.

Contact service. Om with any questions or comments you may have.

Sincerely,

Service Provider

If you have received this message in error or no longer would like to be considered or contacted about clinical trials please go to http://www.servec.scom/remove

In order to evaluate whether you may be eligible for this study, we will need to review some of your medical history. Are you legally able to provide us with this information for the potential study participant?

Yes, I am the potential study participant

Yes, I am a caregiver for the potential study participant with the ability to provide the potential participant's information for the purpose of seeking enrollment in clinical studies No. I am not legally able to provide this information.

In answering the following questions, "you" or "your" refers at all times to the potential study participant.

Please provide your gender.

- o Male
- o Female

How did you hear about this study?

- o Internet
- o Newspaper Ad
- o Newspaper Article
- o Radio Ad
- o Radio Public Service Announcement
- o TV Ad
- o TV program
- o Physician
- o Friend
- o Support Group
- o Patient Ed Materials
- o Cardiology Newsletter
- Other, please specify:

The purpose of this medical research study is to evaluate the effect of an investigational drug on the ability to reason, remember, imagine, and learn in humans who have already been diagnosed with mild to moderate probable Alzheimer's Disease. You must live with a caregiver or receive daily visits from a responsible caregiver. The caregiver must be familiar with the your recent medical history and be willing to come to 7 doctor visits for a period of 6 months.

After these questions are answered we may be able to refer you to a research site for further screening. After the site reviews your responses to the screening questions, a nurse or other person at the research facility will be calling you. At that time, it will be determined if a first visit should be scheduled to determine whether this study is appropriate for you.

Have you been diagnosed with Alzheimer's disease?

- o Yes
- o No

Have you experienced a deterioration in memory over at least the last 6 months?

=16 15A



- o Yes
- o No

Click the box next to the following if you have experienced a decline in any of the following in at least the last 6 months:

- o orientation
- o judgement
- o problem solving
- o functioning in community affairs
- o functioning in home or hobbies
- o functioning in personal care

Do you live in a residential home?

- o Yes
- o No

Click the box next to the person who will serve in the role of Caregiver:

I am the Caregiver

Friend

Relative

Paid personnel

No Caregiver

1. Please enter your date of birth:

Day

Month

Year (pull-down boxes)

- ☐ If female, continue with question 2
- ☐ If male, continue with question 6
- 2. Are you / Is (Patient) surgically sterile or post-menopausal for 1 year or more?
 - o Yes continue with question #6

No – continue with question #3

- 3. Do you / Does (Patient) have any other neurological conditions such as:
 - o Parkinson's disease
 - o Pick's disease
 - o Huntingtons chorea
 - o Down's syndrome
 - o Creutzfeldt-Jacob disease
 - o Other_____
- 4. Do you now or did you at any time, have one or more of the following conditions resulting in your memory or *cognitive* impairment:

F16. 15B

- o Major head injury
- o Injury caused by trauma such as boxing
- Vitamin deficiency
 - o Type [drop down menu]
- o Brain abscess
- o Syphilis
- o Meningitis
- o AIDS
- o Brain cancer
- o Thyroid, parathyroid, or pituitary disease
- o Cushing's syndrome
- Kidney failure
- o Uncontrolled diabetes
- o Mental retardation
- 5. Do you have a history of any of the following:
 - O Stroke within the past 12 months
 - o Epilepsy or convulsions (Childhood convulsions caused by fever continue)
 - o Major depression
 - o Stomach ulcer that is currently being treated
 - o Liver, kidney, or lung disease
 - o Kidney stones
- 6. Have you had a heart attack or coronary artery bypass graft surgery within the past 6 months?
 - o No
 - o Yes
- 7. Do you experience angina (chest pain) that required a change in medication in the past 3 months?
 - o Yes
 - o No
- 8. Has a doctor told you that you have a heart rate that is slow or less than 50 beats per minute?
 - o Yes
 - o No
- 9. Do you take medication for high blood pressure or chronic low blood pressure?
 - o Yes
 - o Medication(s) taken: [drop down menu]
 - o No
 - o Don't know

F16. 15C

10. Do you take any medications for the purpose of treating memory loss such as dementia? o Yes o No 11. Are you allergic to any medications? o Yes Which Medication(s) [drop down menu] o No 12. Are you taking any other medications including vitamins or herbal supplements such as Ginkgo Biloba? o Yes Which Medication(s) [drop down menu] o No 13. Have you ever been enrolled in a research study for galantamine? Yes o No Don't know

14. Have you taken an investigational drug in the past 30 days or are you taking one now?

Yes, am taking an investigational drug now15. How many drinks do you consume in a typical 24-hour period?

No, I have not taken an investigational drug in the past 30 days Yes, I have taken an investigational drug in the past 30 days

- o 1-2 drinks
- o 3-5 drinks
- o 6-8 drinks
- o more than 8 drinks
- 16. Have you/patient had a CT scan or MRI of the head during the last 12 months?

Yes

No



SCREEN #2: PATIENT NOT ELIGIBLE FOR STUDY

We appreciate your interest in this study. Unfortunately, from the information you have provided, you are not a candidate for participation in this study. May we have your permission to contact you in the future with information about this or other studies?

- o Yes, contact me.
- o No, I do not want to be contacted.

F16, 15E



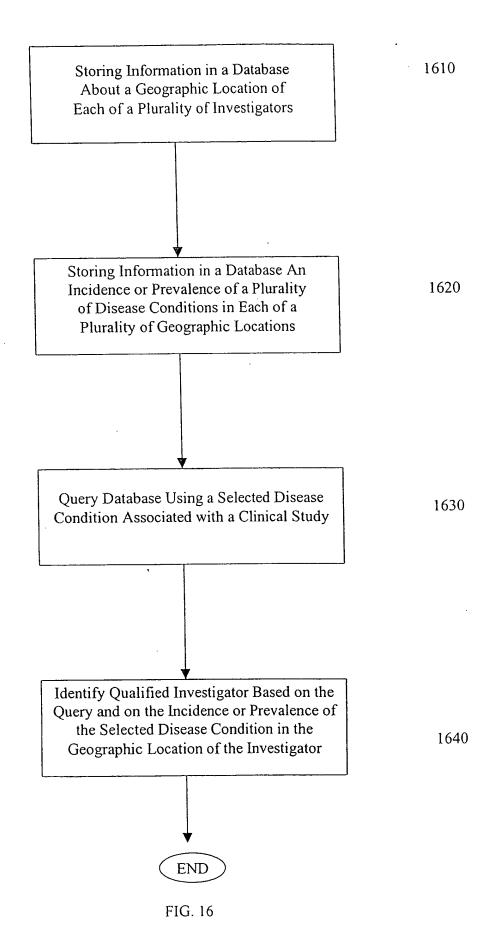
SCREEN #3: PATIENT POTENTIALLY ELIGIBLE FOR STUDY:

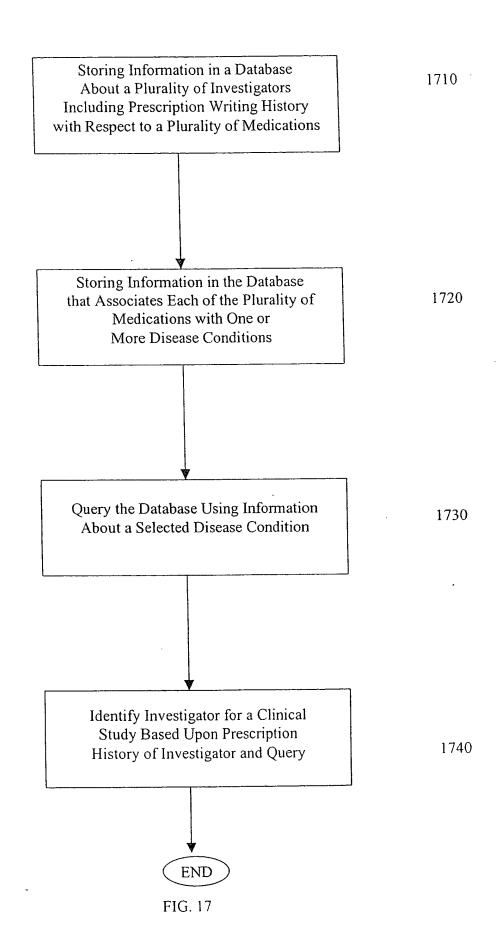
Based on your responses, you may be eligible for the clinical study. We will forward this information to the research site you selected. The research site will contact you shortly to ask you further questions about your health, and possibly to schedule an appointment for the first visit. In the meantime, we will send you a Welcome Kit that contains information about the study. If the site does not contact you within 5-7 business days, please feel free to call the number that will be included in your mailed materials.

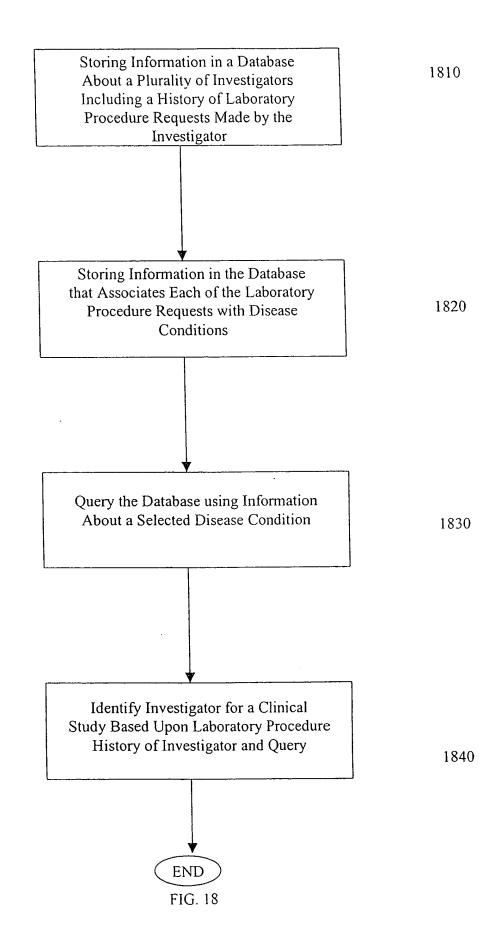
In the event that you do not participate in this particular study, may we have your permission to contact you in the future about other studies?

- o Yes, contact me
- o No, I do not want to be contacted

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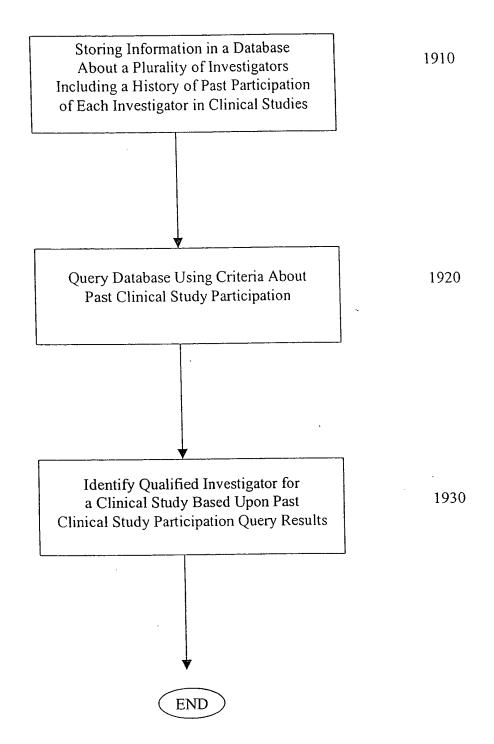
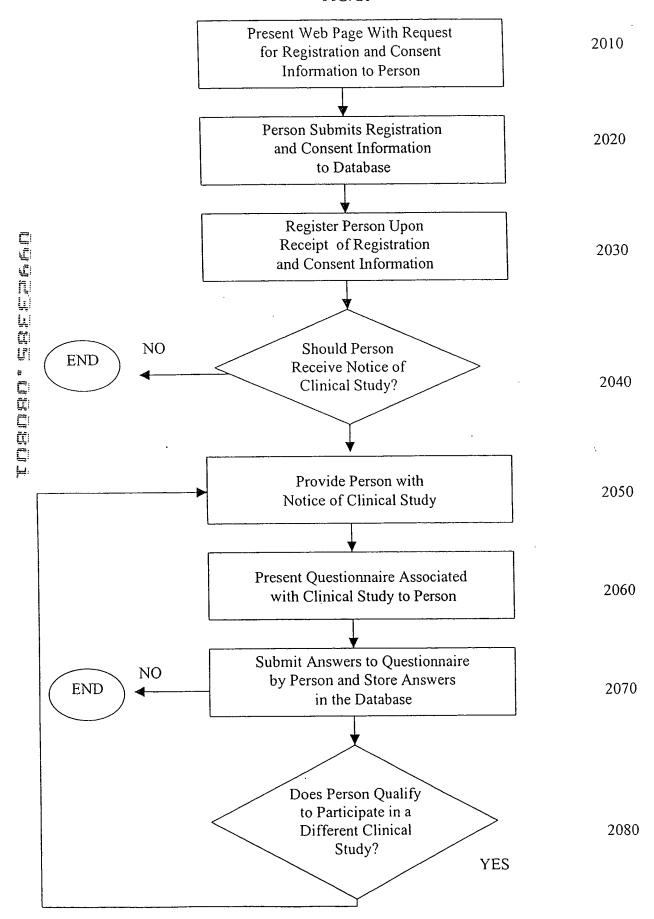
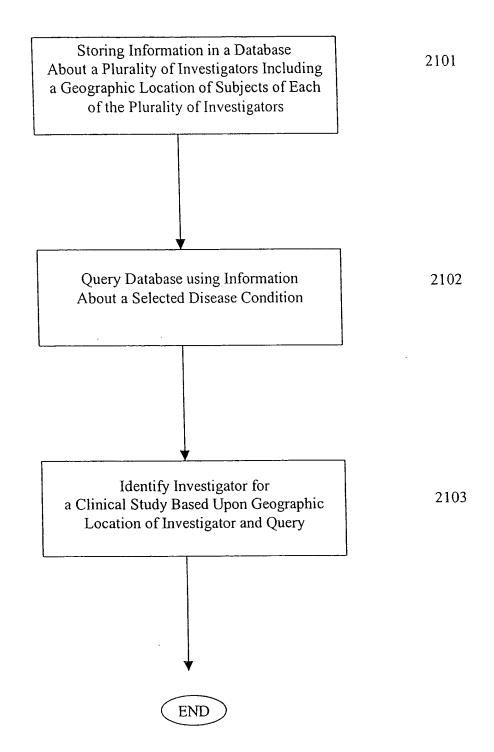


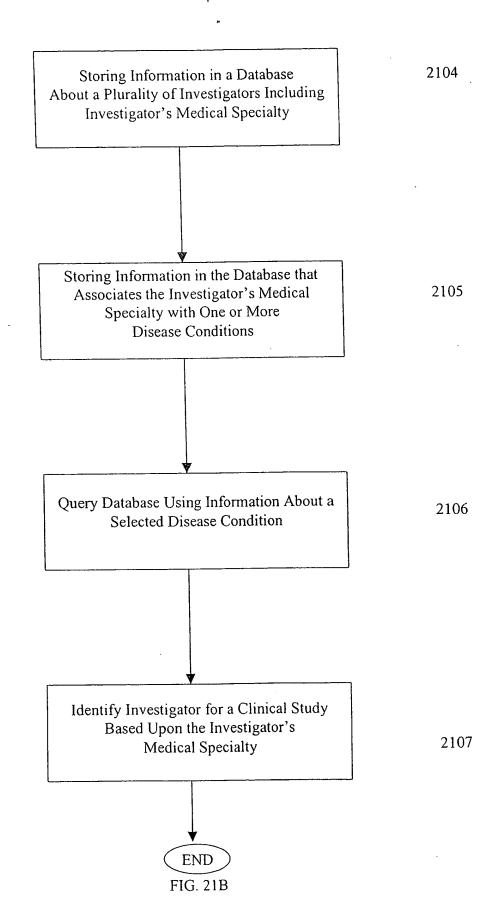
FIG. 20

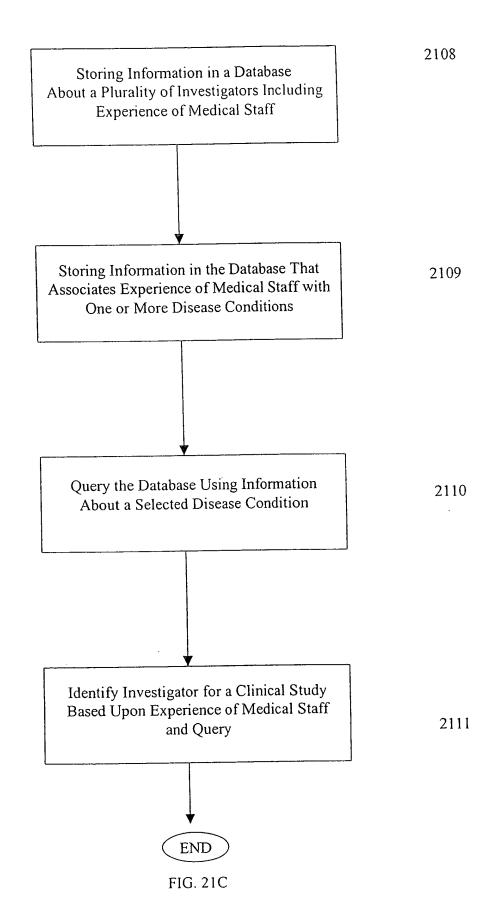












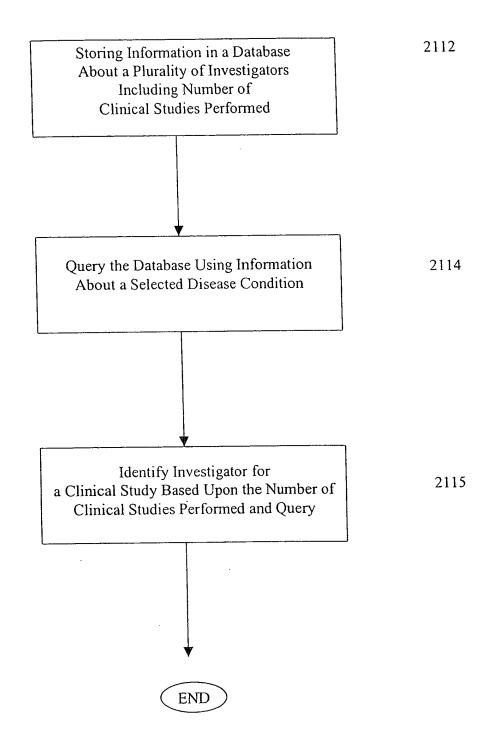
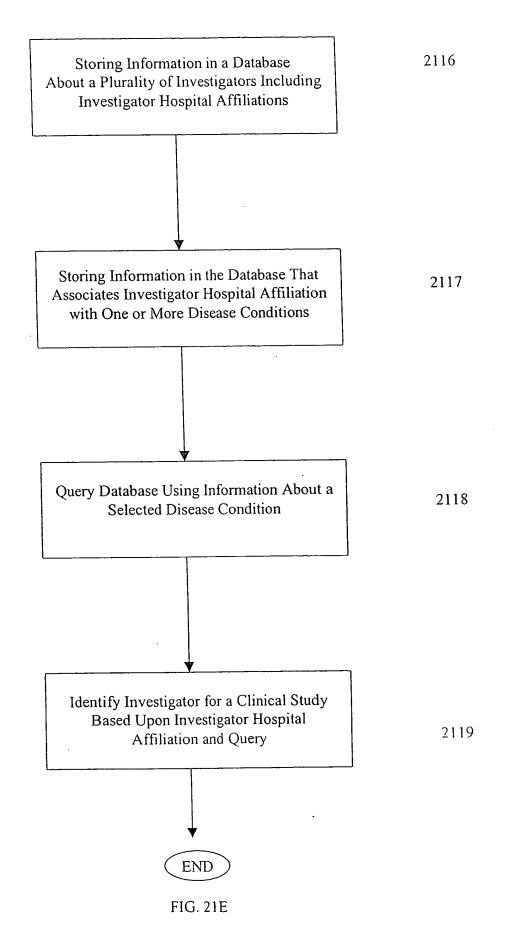
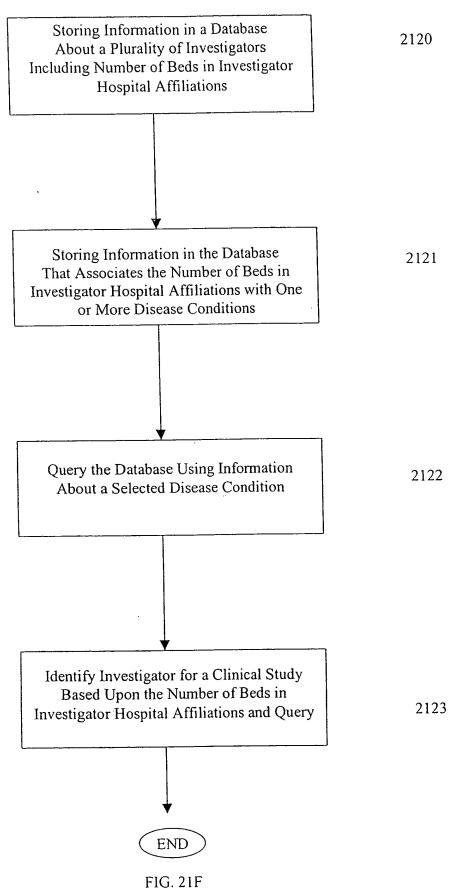


FIG. 21D







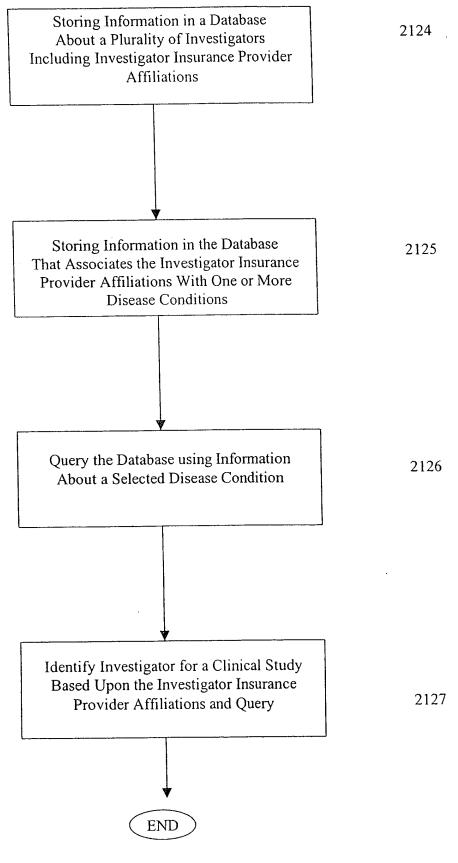
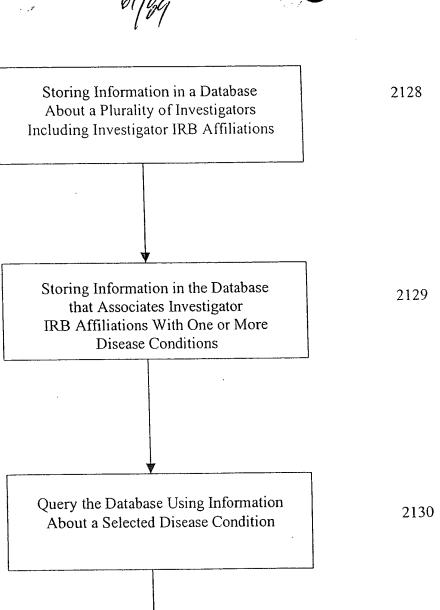


FIG. 21G -



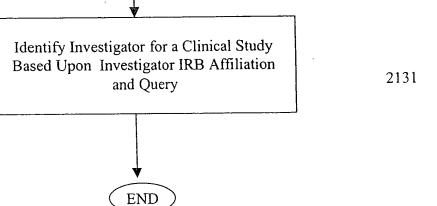
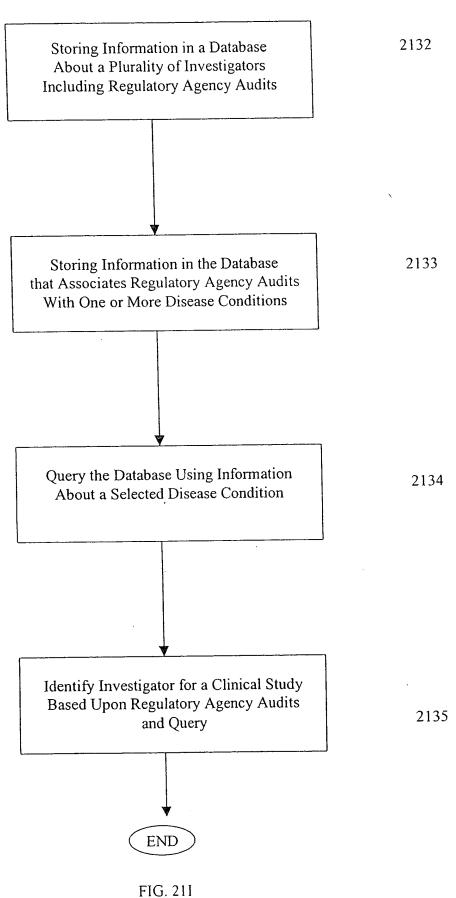
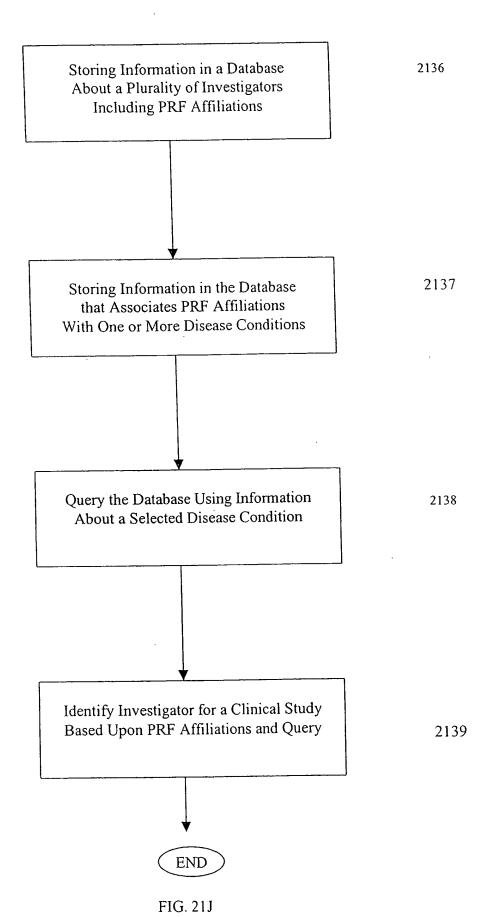
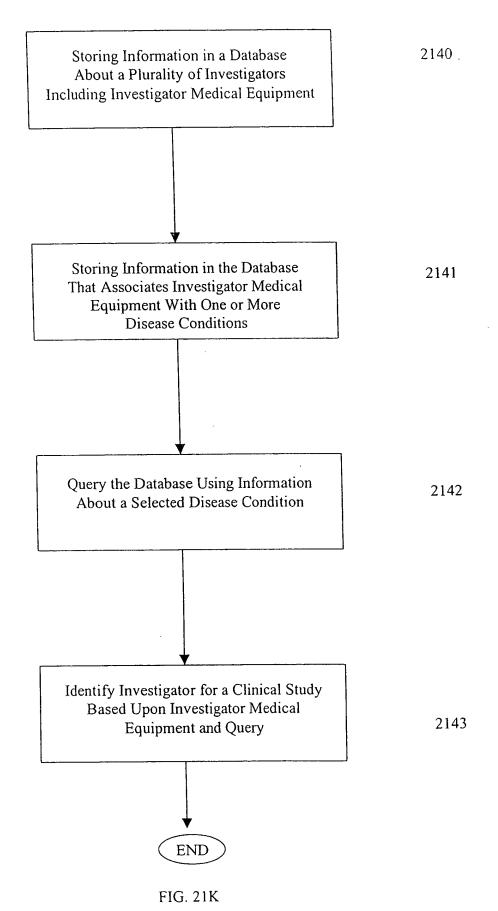


FIG. 21H

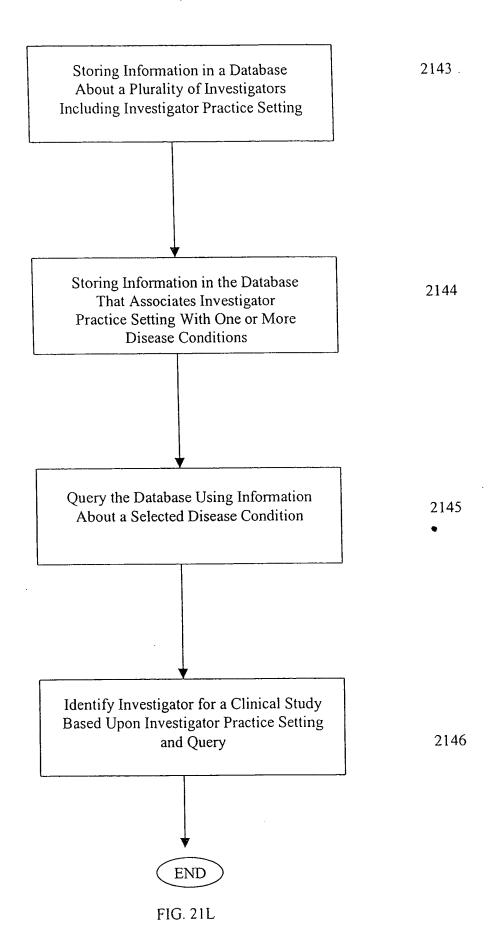


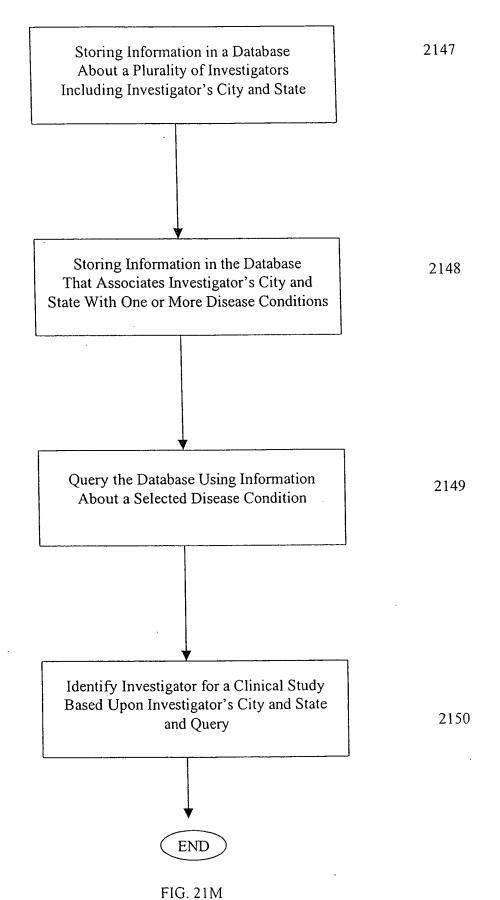


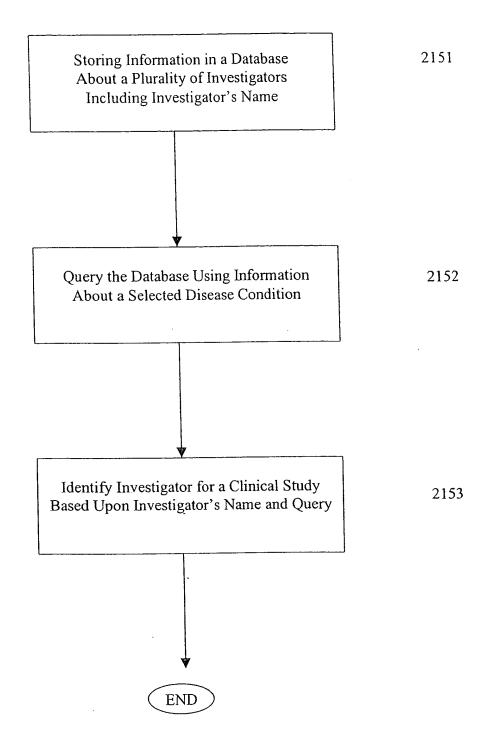












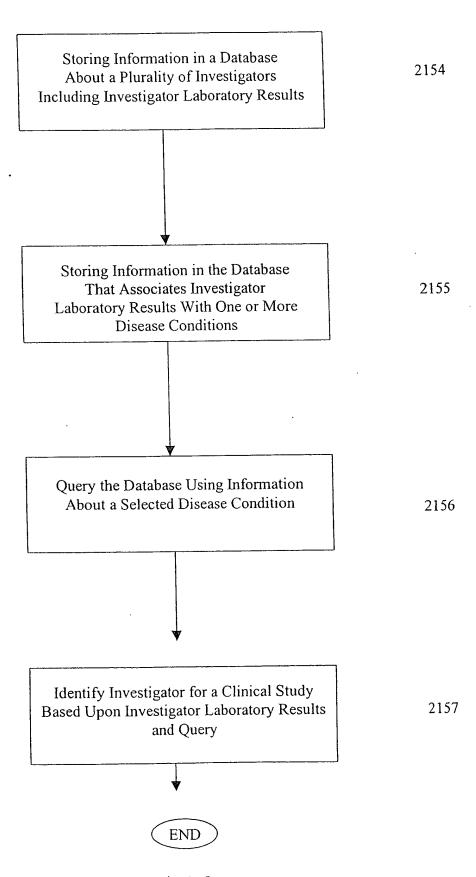


Fig. 210

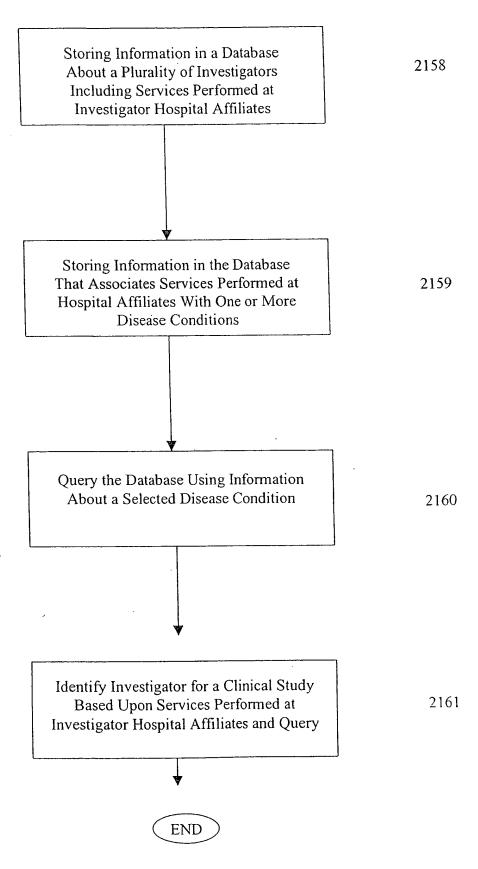


Fig. 21P

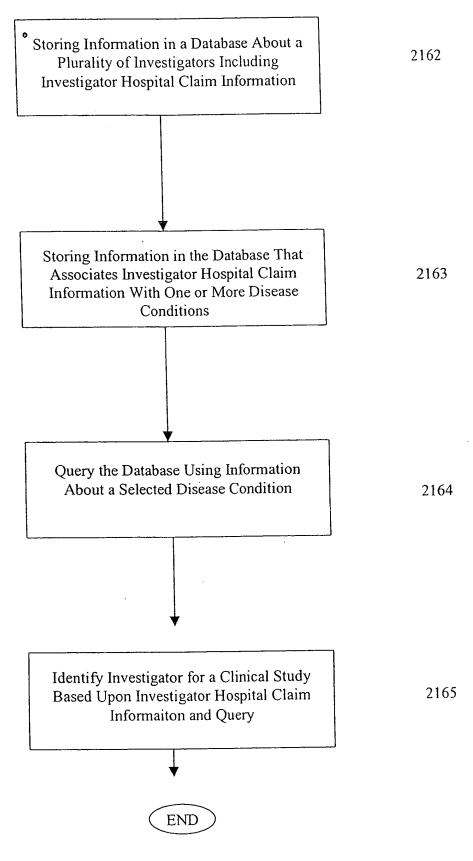
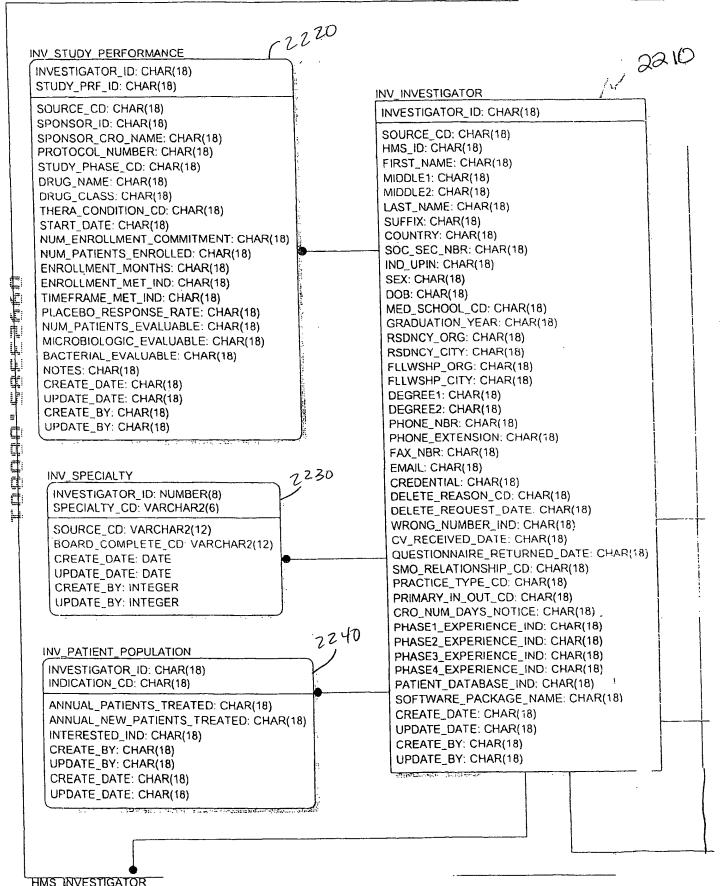
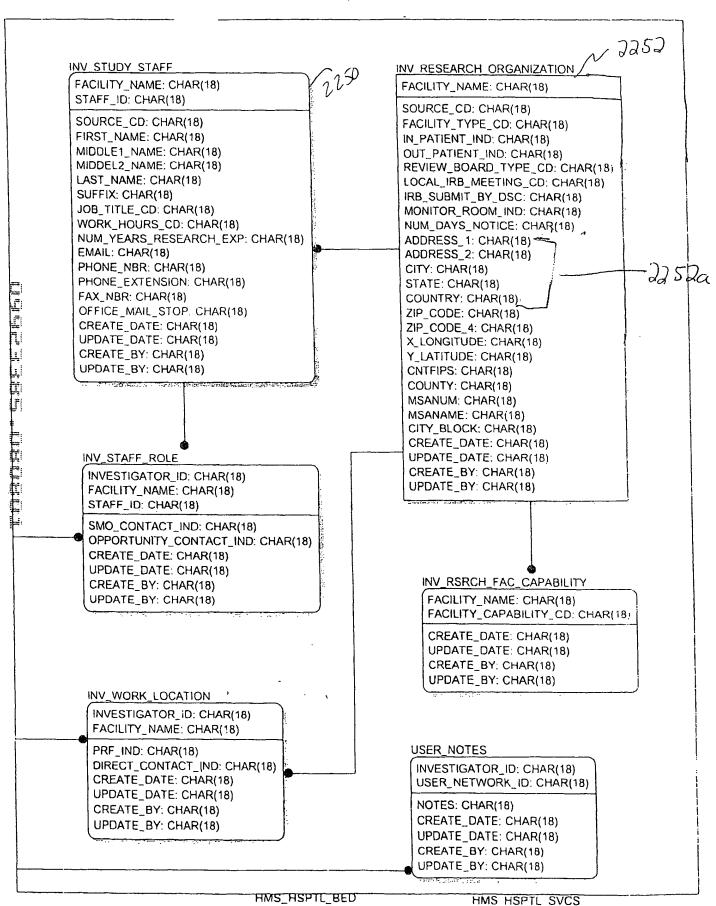


Fig. 21Q



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STLDEV01 -- Display1 / Investigator HMS INVESTIGATOR HMS_HSPTL_AFFLTN -2240 CONTACT_ID: NUMBER(7) CONTACT ID: NUMBER(7) INVESTIGATOR ID: CHAR(18) HMS HOSP ID: VARCHAR2(9) INVESTIGATOR_ID: CHAR(18) HMS ID: VARCHAR2(12) SOC SEC NBR: NUMBER(9) CREATION_DATE: DATE IND UPIN: VARCHAR2(7) UPDATE_DATE: DATE FIRST NAME: VARCHAR2(25) MIDDLE NAME 1: VARCHAR2(25) HMS_SPECIALTY MIDDLE NAME_2: VARCHAR2(25) CONTACT_ID: NUMBER(7) LAST_NAME: VARCHAR2(50) SPECIALTY CD: VARCHAR2(8) SUFFIX: VARCHAR2(10) INVESTIGATOR_ID: CHAR(18) CREDENTIAL: VARCHAR2(3) CREATION_DATE: DATE SEX: VARCHAR2(1) UPDATE_DATE: DATE DOB: NUMBER(10) HMS-eDGA MED SCHOOL CD: VARCHAR2(8) CONTACT_ID: NUMBER(7) GRADUATION_YEAR: VARCHAR2(4) RSDNCY_ORG: VARCHAR2(100) DEA NBR: VARCHAR2(10) RSDNCY_CITY: VARCHAR2(60) INVESTIGATOR_ID: CHAR(18) FLLWSHP_ORG: VARCHAR2(100) CREATION_DATE: DATE FLLWSHP_CITY: VARCHAR2(60) UPDATE_DATE: DATE CREATION DATE: DATE HMS BOARD CERT UPDATE_DATE: DATE CREDENTIAL_2: VARCHAR2(3) CONTACT_ID: NUMBER(7) INTRNSHP NAME: VARCHAR2(100) CERT CD: VARCHAR2(8) INTRNSHP_CITY: VARCHAR2(60) INVESTIGATOR ID: CHAR(18) INTRNSHP_STATE: VARCHAR2(2) CREATION_DATE: DATE UPIN_SANC: VARCHAR2(50) UPDATE_DATE: DATE STATE_SANC: VARCHAR2(50) RSDNCY_STATE: VARCHAR2(2) HMS_LANGUAGE FLLWSHP_STATE: VARCHAR2(2) CONTACT_ID: NUMBER(7) LANGUAGE_CD: VARCHAR2(10) INVESTIGATOR_ID: CHAR(18) HMS_INV_ADDRESS CONTACT ID: NUMBER(7) CREATION DATE: DATE ADDRESS_ID: NUMBER(6) UPDATE_DATE: DATE INVESTIGATOR_ID: CHAR(18) HMS"INSURANCE AFFLIN HMS_ID: VARCHAR2(12) CONTACT_ID: NUMBER(7) TIER: NUMBER(3) INSURANCE_COMPANY CD: VARCHAR2(50) FIRM_NAME: VARCHAR2(100) INVESTIGATOR ID: CHAR(18) ADDRESS_1: VARCHAR2(75) CREATION DATE: DATE ADDRESS 2: VARCHAR2(75) UPDATE_DATE: DATE PHONE NBR: NUMBER(15) HMS GRP UPIN FAX_NBR: NUMBER(15) CITY: VARCHAR2(35) CONTACT_ID: NUMBER(7) STATE: VARCHAR2(2) GRP UPIN: VARCHAR2(8) ZIP_CODE: NUMBER(10) INVESTIGATOR ID: CHAR(18) ZIP_CODE_4: NUMBER(4) CREATION_DATE: DATE X_LONGITUDE: NUMBER(15) UPDATE_DATE: DATE Y LATITUDE: NUMBER(15) HMS_EMPLYR_TAX_TD MSANUM: NUMBER(12) MSANAME: VARCHAR2(45) CONTACT_ID: NUMBER(7) COUNTY: VARCHAR2(30) EMPLR_TAX_ID: NUMBER(10) CNTFIPS: NUMBER(12) INVESTIGATOR ID: CHAR(18) CITY BLOCK: VARCHAR2(30) CREATION_DATE: DATE CREATION_DATE: DATE UPDATE_DATE: DATE UPDATE_DATE: DATE



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STLDEV01 - Display1 / Investigator

REPIAB_SVCS: VARCHAR2(1)
RESPIR_SVCS: VARCHAR2(1)
SELFCARE_SVCS: VARCHAR2(1)
SKNLT_SVCS: VARCHAR2(1)
SOCSVC_SVCS: VARCHAR2(1)
SPEECH_SVCS: VARCHAR2(1)
THERD_SVCS: VARCHAR2(1)
TRAUMA_SVCS: VARCHAR2(1)
XRADT_SVCS: VARCHAR2(1)
CREATION_DATE: DATE
UPDATE_DATE: DATE

Benefit and Apple Control of the Manager

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STLDEV01 - Display1 / Investigator

CONTACT ID: NUMBER(7)

CONTACT_ID: NUMBER(7)
HMS_HOSP_ID: VARCHAR2(9)
INVESTIGATOR_ID: CHAR(18)

HMS STF BEDS: NUMBER(9) HMS_HSP_BEDS: NUMBER(9) HMS_TOT_BEDS: NUMBER(9) HMS_STRM_BEDS: NUMBER(9) HMS_LTERM_BEDS: NUMBER(9) HMS_MDSRG_BEDS: NUMBER(9) HMS ICU_BEDS: NUMBER(9) BEDS OK: VARCHAR2(5) ICU BEDS: NUMBER(9) CCU BEDS: NUMBER(9) SICU_BEDS: NUMBER(9) NICU_BEDS: NUMBER(9) NINT_BEDS: NUMBER(9) PICU BEDS: NUMBER(9) PEDI_BEDS: NUMBER(9) OBGN BEDS: NUMBER(9) PSYC BEDS: NUMBER(9) BURN_BEDS: NUMBER(9) ALCH_BEDS: NUMBER(9) REHB_BEDS: NUMBER(9) OTHR_BEDS: NUMBER(9)

CREATION_DATE: DATE

UPDATE_DATE: DATE

CONTACT_ID: NUMBER(7)
HMS_HOSP_ID: VARCHAR2(9)
INVESTIGATOR_ID: CHAR(18)

HMS HSPTL

HSPTL_NAME: VARCHAR2(100)
DEPT_NAME: VARCHAR2(50)
BRANCH_NAME: VARCHAR2(50)
ADDRESS_1: VARCHAR2(75)
ADDRESS_2: VARCHAR2(75)

LISTATE: VARCHAR2(2) ZIP_CODE: VARCHAR2(6) ZIP_CODE_4: VARCHAR2(4)

CITY: VARCHAR2(25)

PHONE_NBR: VARCHAR2(13)

CEO: VARCHAR2(50) FIPS5: VARCHAR2(10)

COUNTY: VARCHAR2(50)
MSANUM: VARCHAR2(12)
MSANAME: VARCHAR2(50)

CENSUS_ID: VARCHAR2(20)
X_LONGITUDE: VARCHAR2(15)

Y_LATITUDE: VARCHAR2(15)
SRVC_CD: VARCHAR2(5)

SRVC_CD: VARCHAR2(5)

CTRL_CD: VARCHAR2(5)
LOS_CD: VARCHAR2(5)

UNV_HSPTL_IND: VARCHAR2(1) TCH_HSPTL_IND: VARCHAR2(1)

TEACHHOSP_IND: VARCHAR2(1)

RESIDENCY_IND: VARCHAR2(1)
MED_SCHL_IND: VARCHAR2(1)

ALLIED SCHL_IND: VARCHAR2(1)

JCAHO_IND; VARCHAR2(1)

MEDICARE_IND: VARCHAR2(1)

CANCERCTR_IND: VARCHAR2(1) CLOSED_IND: VARCHAR2(1)

CREATION_DATE: DATE

UPDATE_DATE: DATE

HMS_LICENSE

CONTACT_ID: NUMBER(7)
LICENSE_STATE_CD: VARCHAR2(2)
INVESTIGATOR ID: CHAR(18)

LICENSE_YEAR: NUMBER(4)
CREATION_DATE: DATE
UPDATE_DATE: DATE

HMS HSPIL SVCS

CONTACT_ID: NUMBER(7)
HMS_HOSP_ID: VARCHAR2(9)
INVESTIGATOR ID: CHAR(18)

INVESTIGATOR_ID: CHAR(18) AIDS_SVCS: VARCHAR2(1) ANSTH_SVCS: VARCHAR2(1) ANGPLSTY_SVCS: VARCHAR2(1) BLOODBNK_SVCS: VARCHAR2(1) BMTRNSPL SVCS: VARCHAR2(1) BURNCTR_SVCS: VARCHAR2(1) CRDCTH_SVCS: VARCHAR2(1) CVSRGY_SVCS: VARCHAR2(1) CHIRO_SVCS: VARCHAR2(1) CLPSY_SVCS: VARCHAR2(1) CT_SVCS: VARCHAR2(1) DENTL_SVCS: VARCHAR2(1) ULTRSND_SVCS: VARCHAR2(1) DIETRTY_SVCS: VARCHAR2(1) ECARD_SVCS: VARCHAR2(1) ECONV_SVCS: VARCHAR2(1) EMRGCY_SVCS: VARCHAR2(1) ESWL_SVCS: VARCHAR2(1) LABAN_SVCS VARCHAR2(1) HEART_SVCS: VARCHAR2(1) HRTLUNG_SVCS: VARCHAR2(1) HEMDIAL_SVCS: VARCHAR2(1) HOMCRE_SVCS. VARCHAR2(1) HOSPCE_SVCS: VARCHAR2(1) CCU_SVCS: VARCHAR2(1) ICU_SVCS: VARCHAR2(1) KIDNEY_SVCS: VARCHAR2(1) LABCLNC_SVCS: VARCHAR2(1) . LIVER SVCS: VARCHAR2(1) LUNG_SVCS: VARCHAR2(1) MEGVRAD SVCS. VARCHAR2(1) NEONUNT_SVCS: VARCHAR2(1) NICU_SVCS: VARCHAR2(1) MRI_SVCS: VARCHAR2(1) NEURO SVCS: VARCHAR2(1) NSURG_SVCS: VARCHAR2(1) NUCMED_SVCS: VARCHAR2(1) OBSRVA_SVCS: VARCHAR2(1) OBSTE SVCS: VARCHAR2(1) OCCTH_SVCS: VARCHAR2(1) OPNHT_SVCS: VARCHAR2(1) OPTOM_SVCS: VARCHAR2(1) ORGBANK_SVCS: VARCHAR2(1) ORGAN_SVCS: VARCHAR2(1) OUTPAT_SVCS: VARCHAR2(1) OUTSRG SVCS: VARCHAR2(1) PANCR_SVCS: VARCHAR2(1) PEDIAT_SVCS: VARCHAR2(1) PHARM_SVCS: VARCHAR2(1) PHYTH SVCS: VARCHAR2(1) PSTOP_SVCS: VARCHAR2(1) PSYED_SVCS: VARCHAR2(1) PULMON_SVCS: VARCHAR2(1) RADIM SVCS: VARCHAR2(1)

RECTH_SVCS: VARCHAR2(1)

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FDA_1572_STAT

CONTACT_ID: NUMBER(8)
INVESTIGATOR_ID: CHAR(18)

NUM_TRIALS_LAST5: INTEGER
NUM_TRIALS_LAST4: INTEGER
NUM_TRIALS_LAST3: INTEGER
NUM_TRIALS_LAST2: INTEGER
NUM_TRIALS_LAST1: INTEGER
TOTAL_TRIALS_LIFETIME: INTEGER
FIRST_YEAR: INTEGER
LAST_YEAR: INTEGER

FDA_1572

UPDATE_DATE: DATE:

CONTACT_ID: NUMBER(7) FDA_1572_ID: NUMBER(7) INVESTIGATOR_ID: CHAR(18)

HMS_ID: VARCHAR2(12)

LAST_NAME: VARCHAR2(100)
FIRST_NAME: VARCHAR2(25)
MIDDLE_INITIAL: VARCHAR2(1)
SUFX: VARCHAR2(5)
CRED1: VARCHAR2(8)
ORGNAME: VARCHAR2(100)
ADDRESS: VARCHAR2(100)
CITY: VARCHAR2(35)
STATE: VARCHAR2(2)
ZIP_CODE: VARCHAR2(14)
COUNTRY: VARCHAR2(60)
YEAR: NUMBER(4)
RECEIPT_DATE: DATE
RECEIPT_YEAR: NUMBER(4)
ORG_TYPE: VARCHAR2(3)

CREATION_DATE: DATE

FDA_483

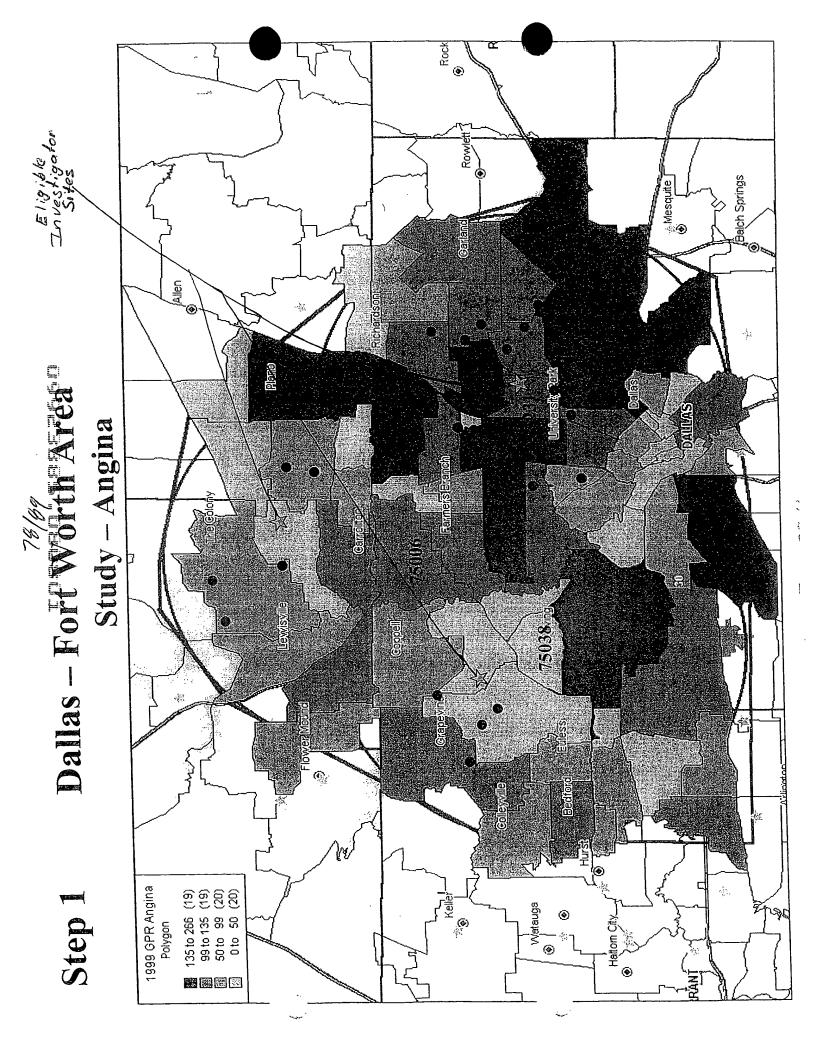
CONTACT_ID: NUMBER(7)
FDA_DFCNCY_ID: NUMBER(8)
CONTACT_ID: NUMBER(7)
INVESTIGATOR_ID: CHAR(18)

HMS_ID: VARCHAR2(12)
LAST_NAME: VARCHAR2(100)
FIRST_NAME: VARCHAR2(25)
ORG: VARCHAR2(100)
ADDRESS: VARCHAR2(100)
CITY: VARCHAR2(35)
STATE: VARCHAR2(2)
ZIP_CODE: VARCHAR2(14)
COUNTRY: VARCHAR2(60)
INSPCTN_DATE: DATE
CLSSFCTN_TYP: VARCHAR2(2)
CLSSFCTN_CD: VARCHAR2(5)
DFCNCY_CD: NUMBER(2)
CREATION_DATE: DATE

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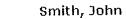
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Case Study - Angina

Rock Rowlett Balch Springs Step 2 Investigator Recruitment / Screening 135 to 266 (19) 99 to 135 (19) 50 to 99 (20) 0 to 50 (20) 1999 GPR Angina Polygon /vjetauga





Specialty Cardiovascular Disease Internal Medicine



Primary Research Facility Trial Experience Study Stall Contact Information Provider Hospital

Yellow = ABC Pharma Trial

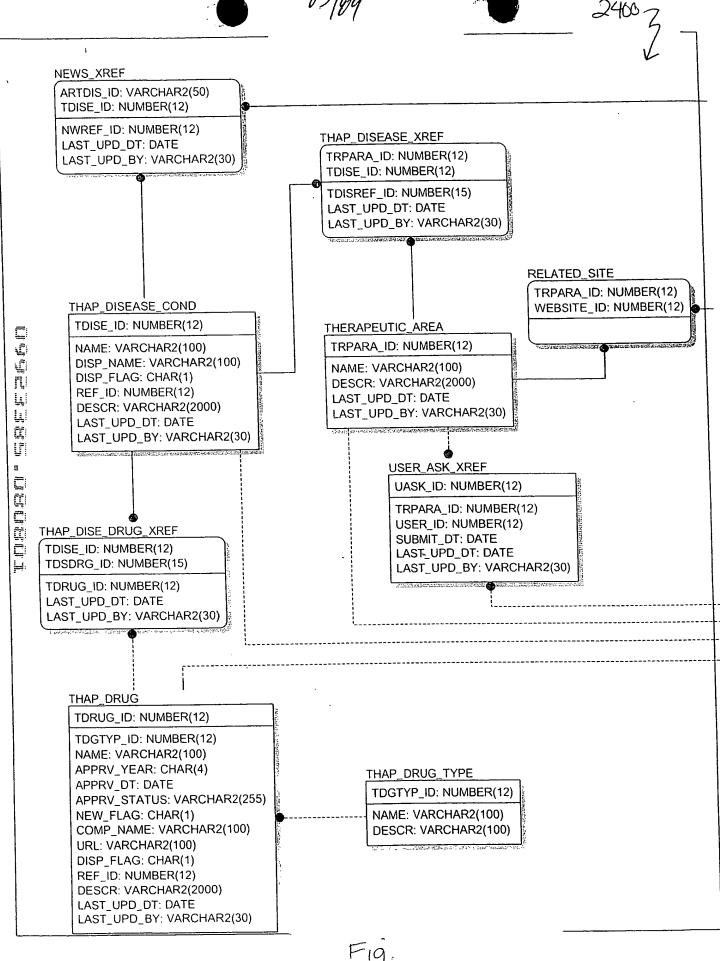
CTTLLLGT.CECTL

Indication	Start Date	Enrollment Commitment	Evaluable Patients	Timeframe (months)	Enrollment Percentage	ABC Pharma Rank
APT	1/15/2001	12	8	12	70%	4
CHF	11/1/2000	10	9	9	90%	
CHF	10/5/2000	10	9	9 /	90%	:
CHD	7/1/2000	8	3	6	40%	2
CAD	6/1/1999	15	12	6	80%	
CHT	2/15/1999	8	7	1,0	90%	4 \
CHF	3/1/1998	10	8	/12	80%	3.\
CHD	3/22/1997	6	4	10	60%	
CHD	6/1/1996	8	6	10	80%	

Aggregated data (2302)

Data supplied by sponsor viewing 5creen (2304)

Fig. 23



F19. 24A



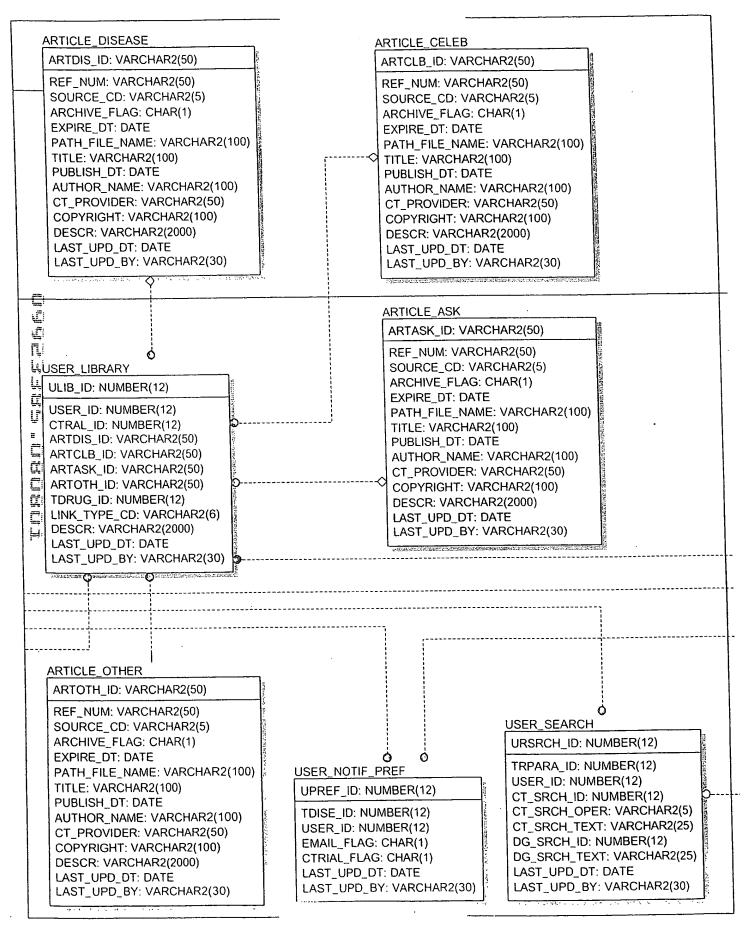
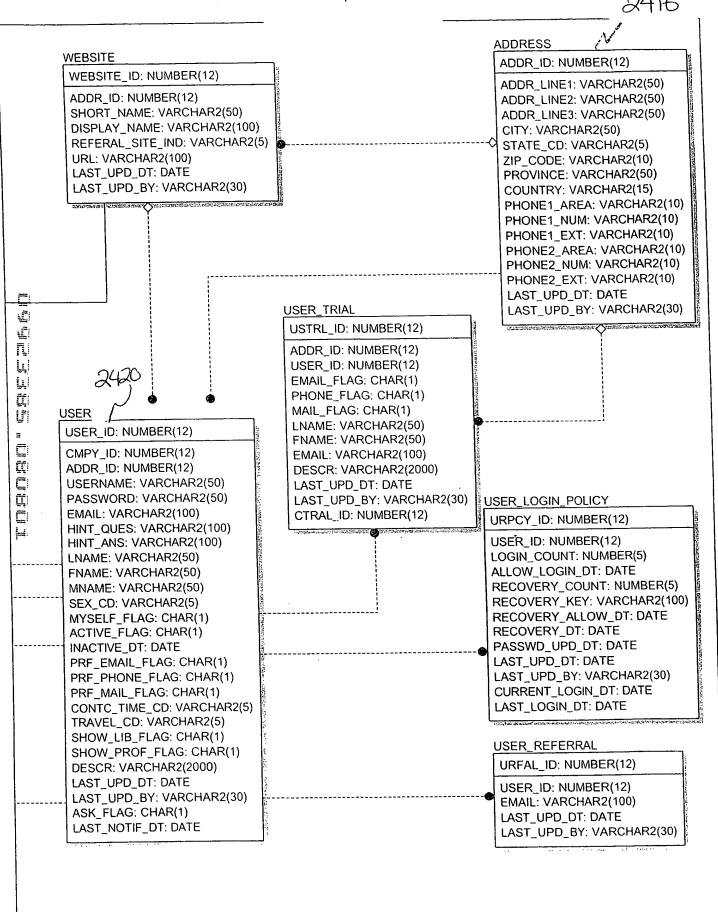


Fig. 24B



F19. 24C





CONTYP_ID: NUMBER(12) NAME: VARCHAR2(100) DESCR: VARCHAR2(100)

ACURIAN_NOTIFICATION

NOTIF_ID: NUMBER(12)

NOTIF_TYPE: VARCHAR2(100) NOTIF_DESC: VARCHAR2(100) LAST_NOTIF_DT: DATE

ACURIAN PUBLISH

PUBLISH_ID: NUMBER(12) CONTYP_ID: NUMBER(12) PUBLISH_DATE: DATE TRPARA_ID: NUMBER(12)

Fig. 24D

ACULN_COMPANY

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COMPANY_ID: NUMBER(8)

DESCRIPTION: VARCHAR2(132) COMPANY_NAME: VARCHAR2(32)

TYPE_CD: VARCHAR2(6)

K 2560

ACR MRGD TRIAL LISTING

SOURCE_CD: VARCHAR2(6)

TRIAL_LISTING_ID: VARCHAR2(30)

SPONSOR COMPANY_ID: NUMBER(8)

HEADER_TXT: VARCHAR2(200)

DETAIL_TXT: BLOB(4000)

DETAIL_TXT_URL: VARCHAR2(200) SORT_PRIORITY_CD: VARCHAR2(6)

DISPLAY_IND: VARCHAR2(1)

DISPLAY_START_DATE: DATE

DISPLAY_END_DATE: DATE

CREATE_DATE: DATE

UPDATE_DATE: DATE

ACR MRGD_TRIAL_INDICATION

SOURCE_CD: VARCHAR2(6)

TRIAL_LISTING_ID: VARCHAR2(30)

THERAPEUTIC_AREA_CD: VARCHAR2(6)

INDICATION_CD: VARCHAR2(6)

ACR_MRGD_TRIAL_SITE

SOURCE CD: VARCHAR2(6)

TRIAL_LISTING_ID: VARCHAR2(30)

TRIAL_SITE_ID: NUMBER(8)

SITE_TXT: VARCHAR2(800)

SITE_TXT_URL: VARCHAR2(200)

STREET1: VARCHAR2(100)

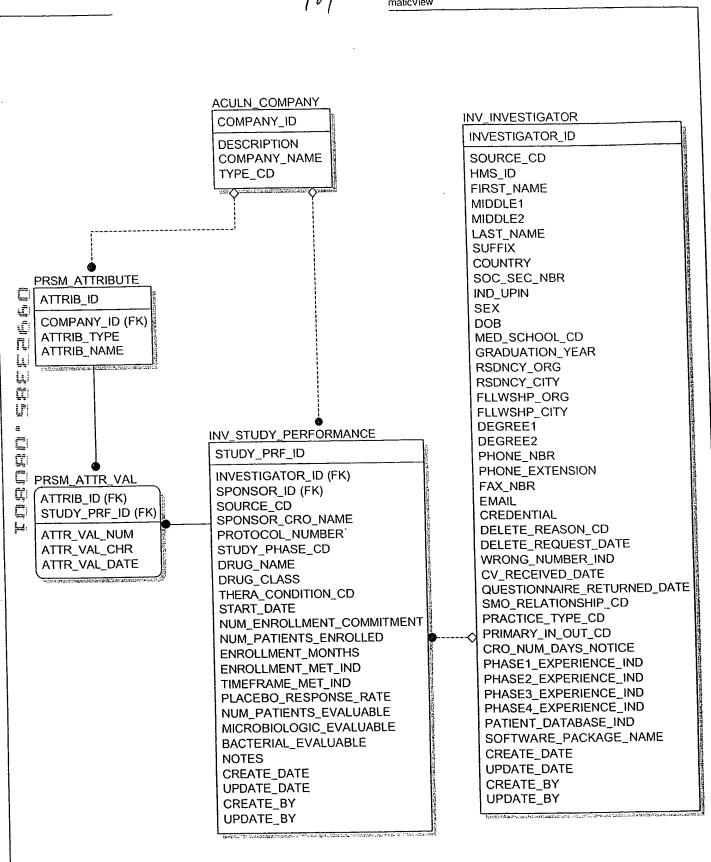
STREET2: VARCHAR2(100)

CITY: VARCHAR2(30)

STATE: VARCHAR2(2) ZIP: NUMBER(5)

ZIP4: NUMBER(4)

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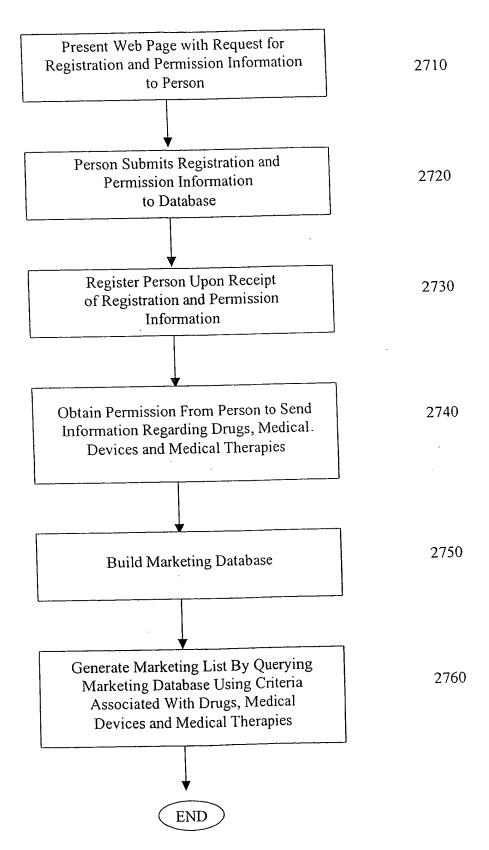


FIG. 27